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**From:** Shams, Dahnish [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B7037E39BB6341C8850BCDC61BF9D65A-SHAMS, DAHN]  
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**Subject:** News Update: Rejecting Industry Calls, EPA Continues To Advance ETBE Risk Assessment (Inside EPA)

Risk Policy Report - 04/29/2014

## Rejecting Industry Calls, EPA Continues To Advance ETBE Risk Assessment

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Posted: April 28, 2014

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EPA's influential Integrated Risk Information System (IRIS) program is planning to complete its assessment of the human health risks of the little-used fuel oxygenate ethyl tert-butyl alcohol (ETBE), despite industry calls to shelve the analysis and focus on higher priority substances that are marketed for use in the United States.

Ken Olden, director of EPA's National Center for Environmental Assessment (NCEA), who heads the IRIS program, told an IRIS bimonthly stakeholder meeting April 23 that staff will complete the ETBE assessment. "We went back and we checked, and there is a request, there is a need for ETBE [to be assessed]. And we're continuing with the assessment," Olden said.

His announcement follows a series of calls from industry officials urging EPA to drop its assessment. The Japanese Petroleum Industry Technology and Research Institute, Inc. (PITRI), whose officials met with EPA earlier this year, said in a letter prior to the meeting that it has "serious concerns with the [EPA] decision to proceed with an [IRIS] assessment of [ETBE]."

The letter, written by PITRI's attorney, Lynn Bergeson, says that EPA should "re-evaluate its apparent decision to move forward with this assessment and [we] believe . . . that ETBE should never have been determined to meet the criteria for assessment." *The letter is available on InsideEPA.com. (Doc. ID: 2468947)*

"Given all the many priority assessments EPA is challenged to complete, we urge EPA to focus on substances of a higher priority and not direct its limited resources to a substance that is neither marketed in the United States nor for which there is need for an IRIS assessment."

And at the last bimonthly IRIS stakeholder meeting in December, domestic fuel interests questioned Olden publicly about the relevance of producing an IRIS assessment for ETBE. Representatives of the American Petroleum Institute (API) and others questioned why ETBE was selected for assessment in the IRIS program. They noted that EPA has never certified the substance for use as an oxygenate after concerns over leaks of a similar chemical, methyl tert-butyl ether (MTBE), which the agency is already assessing.

Like PITRI, they also argued that IRIS resources would be better spent elsewhere, saying the chemical was not used in the U.S. as an oxygenate, and has no other known uses.

After the industry remarks, Olden raised the possibility that the assessment, a decade in the making, would be scuttled. Olden questioned staff about why the assessment remained on the IRIS to-do list if it was not in use in the country, and assured meeting attendees that he would investigate the matter (*Risk Policy Report*, Dec. 17).

But Olden told the April 23 meeting that while he "heard what was said at [the December] meeting . . . the information was not correct." He said the program assessed the relevancy of completing the assessment and found it is still needed.

Sources say that one EPA program office has a priority on the assessment and two other programs are also interested in the assessment. Vincent Coglianò, the director of IRIS, told the December meeting that EPA's air office originally requested the assessment some years ago, when ETBE was under consideration to be included in the gasoline oxygenators program.

Although EPA never approved the substance for use as an oxygenate, occurrence data indicates that the substance is appearing in ground water and soil, suggesting that EPA's water and waste offices may also be seeking the assessment.

**IRIS produces the agency's "gold standard" assessments that are often closely watched** by regulated entities because they can form the basis for agency regulations and other decision making. They are often also lengthy procedures, with some taking a decade or more to complete. At the same time, the program has fallen well short of producing the number of assessments annually that officials have sought.

To address the concerns, the program's managers have sought to prioritize and reduce the number of ongoing assessments that staff is handling in order to increase the program's efficiency and output, and meet goals for completing the reviews.

Olden, for example, has said he intends to reduce the number of assessments underway and has also sought internal review of all assessments, including asking EPA program office staff why assessments were nominated and whether they are still needed. Many assessments were delayed or removed from the schedule in order to hasten those considered most important.

The ETBE assessment, already underway since 2004, has also been mired in controversy. It was one of five IRIS assessments that former research chief Paul Anastas stalled or reviewed in 2010 because they referenced data from the controversial Italian laboratory known as the Ramazzini Institute. Industry and other critics argued that the Ramazzini labs' unorthodox methods overestimated the chemicals' cancer risks, and that as a result, EPA should not base its toxicity estimates upon its data.

In its Jan. 21 letter to EPA, PITRI's Bergeson argues that ETBE does not meet the agency's criteria for undertaking a resource-intensive IRIS assessment. Those criteria include potential public health impact; EPA statutory, regulatory, or program-specific implementation needs; availability of new scientific information or methodology that might significantly change the current IRIS information; interest to other governmental agencies or the public; and availability of other scientific assessment documents that could serve as a basis for an IRIS assessment.

Further, she notes that the decision to assess any given chemical substance depends on available resources, adding that the availability of risk assessment guidance, guidelines, and science policy decisions may also have an impact on the timing of EPA's decision to assess a chemical substance.

"PITRI appreciates EPA's limited resources to conduct IRIS assessments and the need, considering those resources, to select substances for assessment that are particularly relevant to EPA or other agencies for the protection of public health through regulatory means. ETBE does not meet these criteria and thus should be dropped from the IRIS program," Bergeson says.

Among other things, she argues that there is no public health or regulatory need for an ETBE assessment, noting that the agency declined to include the substance in its 2009 list of contaminants the agency may want to consider for regulation under the Safe Drinking Water Act.

Further, a 2006 U.S. Geological Survey (USGS) report noted that ETBE was detected "infrequently" in sampled domestic and public drinking water wells, with a detection frequency well below 1 percent at an assessment level of 0.02 micrograms per liter (ug/L), the letter says.

But the chemical does appear -- though generally at levels less than 0.2 ug/L of water -- in USGS groundwater monitoring. USGS' National Water-Quality Assessment Program in 2006 published "Volatile Organic Compounds in the Nation's Ground Water and Drinking-Water Supply Wells," which includes sampling of ETBE in aquifers and wells that provide water to public water systems. In 1,683 aquifer samples, USGS detected ETBE in 0.18 percent of the samples. Similarly, in public wells, of 818 samples, USGS detected ETBE in 0.14 percent.

Additionally, while the chemical may not appear to be a priority from the USGS data, it may pose a hotspot problem. For example, well sampling data from Jacksonville, MD, indicates that wells tested in that area between 2006 and 2010 had widely varying levels of ETBE, some as high as in the thousands of ug/L. The testing was performed following the release of some 26,000 gallons of gasoline from a nearby ExxonMobil gas station in 2006. The data, collected by multiple interested parties including the Maryland Department of the Environment, appear to show that those levels tended to drop dramatically over the testing time span. Numerous other chemicals, often MTBE, accompanied the presence of ETBE in the data.

And California's GeoTracker database, which contains groundwater and soil sampling data at cleanup sites around the Golden State, also indicates a wide variety of levels of ETBE at nearly 600 sites where the chemical was detected in the past three years. GeoTracker shows that the levels of ETBE detected range from 0.97 ug/L at an Arco marine terminal in Long Beach to 4,000 ug/L at a Chevron leaking underground storage tank in Los Angeles.

Of these, more than four-fifths of the sites were less than 10 ug/L. As in the Jacksonville, MD data, GeoTracker shows that ETBE is generally detected along with other chemicals, often including MTBE. -- *Maria Hegstad*

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Dahnish Shams

Science Communications

National Center for Environmental Assessment

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W: 703-347-0167

